

## REMARKS

Claims 1, 3, 7, 9-16, and 25 are pending in this application. Claim 25 is rejected under 35 U.S.C. § 102(b) for anticipation by Brown et al. (RE 33,221; hereinafter “Brown”). Claims 1, 3, 7, and 9-12 are rejected under 35 U.S.C. § 102(e) for anticipation by Constantz (U.S. Patent No. 5,962,028; hereinafter “Constantz”). Claims 13-16 are rejected under 35 U.S.C. § 103(a) for obviousness over Constantz. Claim 25 is rejected under 35 U.S.C. § 103(a) for obviousness over Constantz in view of Ison et al. (U.S. Patent No. 5,683,496; hereinafter “Ison”). Claims 1, 3, 7, 9-16, and 25 are rejected under 35 U.S.C. § 103(a) for obviousness over Simkiss et al. (WO 94/02412; hereinafter “Simkiss”) alone, and over Simkiss in combination with Brown. Finally, claims 1, 3, 7, 9-16, and 25 are rejected for obviousness-type double patenting over claims 1-19 and 21 of U.S. Patent No. 6,214,368 (hereinafter “the ‘368 patent”), claims 1-2 of U.S. Patent No. 6,132,463 (hereinafter “the ‘463 patent”), claims 1-21 of U.S. Patent No. 6,027,742 (hereinafter “the ‘742 patent”), claims 1-9 of U.S. Patent No. 6,331,312 (hereinafter “the ‘312 patent”), claims 36-55 of U.S. Patent No. 6,541,037 (hereinafter “the ‘037 patent”), and claims 1-27 of U.S. Patent No. 6,277,151 (hereinafter “the ‘151 patent”). By this reply, Applicants amend claims 1 and 25, and address each of the Examiner’s rejections.

### Support for the Amendment

Support for the amendment to claims 1 and 25 is found in the specification at, e.g., page 4, lines 23-25, and Examples 1 and 2 found on page 31, line 7, through page 33, line 13. Although the present specification does not explicitly describe the calcium phosphate compositions recited in present claims 1 and 25 as being “non-stoichiometric” or as having “less than 2% by weight carbonate ions incorporated into the calcium phosphate crystal structure,” the addition of this term and phrase to present claims 1 and 25 is not new matter. *Ipsis verbis*

disclosure is not necessary to satisfy the written description requirement of 35 U.S.C. § 112.

Instead, the disclosure need only reasonably convey to persons skilled in the art that the inventor had possession of the subject matter in question (*In re Edwards*, 568 F.2d 1349, 1351-52, 196 U.S.P.Q. (BNA) 465, 467 (CCPA 1978)).

Here, the Background of the Invention section on page 2, lines 1-2, of the specification, when describing natural bone, states that “[b]one mineral non-stoichiometry is primarily due to the presence of divalent ions, such as  $\text{CO}_3^{2-}$  and  $\text{HPO}_4^{2-}$ , which are substituted for the trivalent  $\text{PO}_4^{3-}$  ions.” Given this description, one skilled in the art would appreciate that Applicants’ PCA calcium phosphate compositions, which include carbonate ions, would be “non-stoichiometric.” In addition, Examples 1 and 2 of the present specification clearly describe the preparation of PCA calcium phosphate compositions having carbonate ions in the range of 0.5-1.56% by weight incorporated into the calcium phosphate crystal structure during preparation of the calcium phosphate compositions of the present invention.

No new matter is added by the amendment. Applicants reserve the right to pursue broader claims in a continuation application.

#### Rejections under 35 U.S.C. § 102(b)

Claim 25 stands rejected for lack of novelty over Brown. The Examiner states that “Brown et al. disclose a dental restorative cement pastes [sic]...[containing] a mixture of two sparingly soluble calcium phosphates and a dilute aqueous solution...Brown et al disclose methods of manipulating setting times by adding...crystal habit modifiers such as...carbonate” (Office Action, pp. 2-3).

In response to the anticipation rejection, Applicants, by the present amendment, have narrowed claim 25 to recite a method for embedding a prosthetic device at an implant site by applying, to a surface of the prosthesis, a paste that includes a carbonated amorphous calcium phosphate, a poorly crystalline apatitic (PCA) calcium phosphate, and a physiologically acceptable fluid, whereby the paste hardens to form a non-stoichiometric, strongly bioresorbable, poorly crystalline apatitic (PCA) calcium phosphate product that includes less than 2% by weight carbonate ions incorporated into the calcium phosphate crystal structure. Brown does not teach a method using a paste that hardens to form a PCA calcium phosphate having less than 2% by weight carbonate ions incorporated into its crystal structure. Because Brown fails to teach all of the elements of present claim 25, Applicants respectfully request that the rejection of claim 25 under 35 U.S.C. § 102(b) for anticipation by Brown be withdrawn.

Applicants also note that the present amendment to claim 25 incorporates limitations into the claim that were discussed in the Declaration of Dr. Michael Strunk, which was enclosed with the previous Reply to Office Action filed on September 27, 2006. Thus, Applicants invite the Examiner to reconsider the statements made in the Declaration that distinguish present claim 25 over Brown in light of the present amendment.

#### Rejections under 35 U.S.C. § 102(e)

Claims 1, 3, 7, and 9-12 stand rejected under 35 U.S.C. § 102(e) for anticipation by Constantz. The Examiner states that “Constantz discloses a carbonated hydroxyapatite (HA) which is resorbable and a flowable mass that may be administered via a syringe and harden in situ” (Office Action, pp. 6-7).

In response to this rejection, Applicants, by the present amendment, have narrowed independent claim 1 to recite a method for treating a bone defect by implanting a non-

stoichiometric, strongly bioresorbable, synthetic poorly crystalline apatitic (PCA) calcium phosphate that includes less than 2% by weight carbonate ions incorporated into the calcium phosphate crystal structure at an implant site requiring bone growth. Constantz discloses dahllite-like compositions that include between 2% and 10% carbonate (see, e.g., Col. 3, lines 12-14, and Claim 1). Constantz does not teach or suggest the treatment of a bone defect by using a PCA calcium phosphate that includes less than 2% by weight carbonate ions incorporated into its crystal structure. Thus, Constantz fails to teach or suggest all of the elements of present independent claim 1. Applicants respectfully request that the rejection of independent claim 1, and claims 3, 7, and 9-12 dependent therefrom, under 35 U.S.C. § 102(e) for anticipation by Constantz be withdrawn.

#### Rejections under 35 U.S.C. § 103(a)

##### *Constantz Alone*

The Examiner also rejects claims 13-16 under 35 U.S.C. § 103(a) for obviousness over Constantz. As is discussed above, Constantz does not teach or suggest all of the limitations of present claim 1. Because claims 13-16 depend from claim 1, they must also be non-obvious over Constantz (see M.P.E.P. § 2143.03; “If an independent claim is nonobvious under 35 U.S.C. 103, then any claim depending therefrom is nonobvious.” *In re Fine*, 837 F.2d 1071, 5 USPQ2d 1596 (Fed. Cir. 1988)). Applicants respectfully request that the rejection of claims 13-16 under 35 U.S.C. § 103(a) for obviousness by Constantz be withdrawn.

##### *Constantz in view of Ison*

The Examiner also rejects claim 25 under 35 U.S.C. § 103(a) for obviousness over Constantz in view of Ison. Constantz is discussed above. The Examiner states that “Constantz

does not teach the use of amorphous calcium phosphate as the calcium source to make the carbonated hydroxyapatite...[but] Ison teaches [a] storage stable calcium phosphate cement...[made using] amorphous calcium phosphate” (Office Action, pp. 8-9). As is discussed above, Applicants have amended present claim 25 to require the formation of a paste by mixing a carbonated amorphous calcium phosphate, a poorly crystalline apatitic (PCA) calcium phosphate, and a physiologically acceptable fluid; the paste hardens to form a non-stoichiometric, strongly bioresorbable, poorly crystalline apatitic (PCA) calcium phosphate product that includes less than 2% by weight carbonate ions incorporated into the calcium phosphate crystal structure. Neither Constantz nor Ison teaches or suggests the formation of a hardened PCA calcium phosphate having less than 2% by weight carbonate ions incorporated into its crystal structure. Because Constantz and Ison, either singly or in combination, fail to teach or suggest all of the elements of present claim 25, Applicants respectfully request that the rejection of claim 25 under 35 U.S.C. § 103(a) for obviousness over Constantz in view of Ison be withdrawn.

*Simkiss Alone or in Combination with Brown*

Claims 1, 3, 7, 9-16, and 25 also stand rejected under 35 U.S.C. § 103(a) for obviousness over Simkiss alone or in combination with Brown. The Examiner states that “Simkiss et al teach an amorphous calcium phosphate mixed with a crystal inhibitor that hardens to form bone in vivo” (Office Action, p. 10). The crystallization inhibitors disclosed by Simkiss include magnesium ions, pyrophosphate ions, citrate ions, and acrylate ions (see, e.g., page 3 of Simkiss).

As is discussed above, present claims 1 and 25 have been narrowed to require that the PCA calcium phosphate include less than 2% by weight carbonate ions incorporated into the calcium phosphate crystal structure. Simkiss fails to teach or suggest incorporating carbonate ions in any amount into the hydroxyapatite cement composition. Thus, Simkiss alone fails to teach or suggest all of the elements of present independent claims 1 and 25, and claims dependent therefrom.

Brown fails to remedy the deficiencies of Simkiss because it fails to teach or suggest the preparation of a synthetic PCA calcium phosphate that includes less than 2% by weight carbonate ions incorporated into the calcium phosphate crystal structure. Thus, Simkiss and Brown, either singly or in combination, fail to teach or suggest all of the limitations of present claims 1, 3, 7, 9-16, and 25. Applicants respectfully request that the rejection of claims 1, 3, 7, 9-16, and 25 under 35 U.S.C. § 103(a) for obviousness over Simkiss alone or in combination with Brown be withdrawn.

#### Obviousness-type Double Patenting Rejection

The Examiner rejects claims 1, 3, 7, 9-16, and 25 for obviousness-type double patenting over claims 1-19 and 21 of the '368 patent, claims 1-2 of the '463 patent, claims 1-21 of the '742 patent, claims 1-9 of the '312 patent, claims 36-55 of the '037 patent, and claims 1-27 of the '151 patent. In the event the pending claims are found to be otherwise allowable, Applicants will consider the appropriateness of filing a terminal disclaimer to overcome this rejection.

CONCLUSION

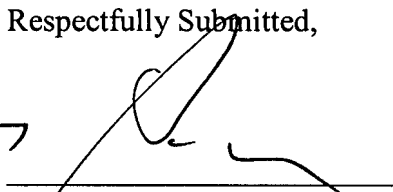
In view of the above remarks, Applicants respectfully submit that the claims are in condition for allowance, and such action is respectfully requested.

Enclosed is a petition to extend the period for replying for three months, to and including March 14, 2007, and a check for the fee required under 37 C.F.R. § 1.17(a).

If there are any additional charges or any credits, please apply them to Deposit Account No. 03-2095.

Respectfully Submitted,

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